

From: Bruce Gordon

Sent: Wednesday, May 02, 2001 10:16 PM

To: tituss@cder.fda.gov

Subject: FDA OTC review of second gen. antihistamines 360901 MAY 10 A7:04

Dear Ms. Titus:

As a practicing Otolaryngologist seeing a high percentage of allergy patients, I am opposed to prematurely releasing the second generation antihistamines for OTC use.

The primary reason for my opposition is that placing these drugs OTC will substantially increase their cost to patients who now participate in prescription plans. This cost increase will decrease utilization of second generation drugs in favor of cheaper, sedating antihistamines. We know that the sedating antihistamines are dangerous for drivers and equipment operators, so that a shift to use of these older drugs will endanger some significant fraction of the public. From my professional experience, I can state that a high fraction of my patients recognize that they are impaired by the older antihistamines. And, driving simulator studies have shown that many people who are not aware of impairment are actually more impaired than they would be by moderate alcohol consumption. I therefore view this proposal as a public health threat, which ought to be rejected by the FDA.

Sincerely,

Bruce R. Gordon, MD, FACS

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Gordon